

SOME THOUGHTS ON CONCEPTS FUNDAMENTAL TO THE DELIVERY OF NUCLEAR SAFETY REGULATION

INTRODUCTION

1. A critical component of a country's decision to pursue a national energy programme which includes nuclear power is a commitment to ensuring that nuclear safety receives the highest priority.
2. Due to the effects of distinct historical, constitutional, legal, political, institutional, social and cultural backgrounds, differences in regulatory oversight exist in most countries with nuclear power programmes. These societally-based differences have resulted in, inter alia:
 - the particular organizational structure of the nuclear regulatory body(ies);
 - the scope and distribution of regulatory responsibilities and functions;
 - the extent of internalization of core capabilities within the regulatory organisation;
 - the degree of political and legal control;
 - the market conditions in the regulated nuclear industries and their impact on availability of resources for safety;
 - the type and extent of licensable activities;
 - the basic approaches of licensees towards regulations;
 - how regulation is affected by the type of nuclear facility, the number of reactor types, or the number of utilities;
 - the nature of funding methods and sources for regulatory activities (e.g.. licensee fees, general tax revenues; and
 - the specific arrangements for public information and public participation in regulatory decisions.
3. These national variabilities have resulted in diversity in the approach to regulation. Some examples of these different approaches include:
 - the amount and type of inspection activities;
 - differences in inspection approaches;
 - the enforcement measures available and the authorities involved (civil and criminal penalties);
 - the specific nature, form, and content of authorisations (or licences) issued by the regulatory body to the operating organisation; and
 - the degree to which:
 - probabilistic methods are applied to regulatory judgements;
 - reliance is placed on the internal control mechanism of licensees and on analysis and calculations performed by licensees;
 - regulatory organisations conduct safety-related research;
 - reliance is placed on inspection;

- reliance is placed on detailed, codified regulations versus general goal setting provisions (guidelines, principles, etc.); and
 - organisational, managerial and other human factor issues are addressed.
4. It is particularly important that these differences are recognised as acceptable alternative approaches within a strong regulatory programme and within the context of the general principles of good regulation.
 5. In 1998-1999 the members of the International Nuclear Regulators Association, undertook to compare and contrast the policy, procedural and institutional bases which characterise their national approaches to nuclear safety regulation. However, as these discussions took place, it became clear that a first step would have to be agreement on common definitions of key concepts, establishing a clear “standard language” from which could be derived a sound understanding of ideas on national approaches to nuclear regulatory. The outcome of this process has been to provide a notional framework for “Concepts Fundamental to Nuclear Safety Regulation”, which would be applicable regardless of specific organisational or infrastructural choices. The first five concepts chosen were:
 - Effective independence
 - Regulatory process
 - Regulatory effectiveness
 - Powers and sanctions
 - Internal quality assurance

EFFECTIVE INDEPENDENCE

Introduction

6. The Convention on Nuclear Safety clearly states that while the prime responsibility for the safety of a nuclear installation rests with the holder of the licence, a regulatory body should be entrusted with the implementation of the legislative and regulatory framework. The regulatory body must therefore have adequate authority, competence and financial and human resources to be able to do this. It also requires that there should be an effective separation between the functions of the regulatory body and those bodies concerned with the promotion or utilisation of nuclear energy. “Effective independence” (or “separation”) directly supports each of the other four concepts, and as such is considered first in this process.

THE COMPONENTS OF INDEPENDENCE

7. The regulatory body should be accountable to the national legislative or executive bodies. In order to ensure their independence, in many countries the senior regulator(s) are appointed by the government. To implement the prime role of the regulator, i.e. ensuring the nuclear licensee carries out its responsibilities for public and worker safety, a decision-making framework that preserves neutrality and objectivity is essential. This neutrality and objectivity is the key of the concept of “independence”. In countries where there is a strong nuclear safety culture, regulatory independence is delivered through a combination of political, legal/statutory, financial, technical, communication, accountability and international components.

The Political Component

8. The regulatory body should be accountable to the national legislative or executive bodies, but independence of regulatory decision-making is an essential criterion of an effective and safe nuclear programme. The political system should ensure that there is effective separation between the regulatory body and those who are responsible for the promotion of the nuclear industry. Protection of independence can be achieved through a variety of means reflecting national cultural and organisational preferences; however, in no system should the regulator be subject to undue influence or pressure, real or perceived, whether it be by the state, the industry, the licensee or other interested parties such as individual politicians, the public and the media.
9. To protect regulatory independence, there should be separation of regulatory policy or functions from energy policy, whether promotional or management policy.
10. The rules for the appointment of the senior regulator(s) can influence regulatory independence, therefore it is important to be clear on the selection criteria for the post. In some countries appointments are made by government, parliamentary vote or ratification, in others the establishment of multiple appointees (e.g. to a commission) provides a non-partisan balance of viewpoints. It is important to recognise that the perception of independence of the regulator (the senior regulator and their staff) can be significantly influenced through ties, or lack of ties, to the nuclear establishment.

The Legal Component

11. The legal framework should ensure that there is effective separation between the regulatory body and those who are responsible for the promotion of nuclear energy. Powers of the regulatory body should be underpinned by the legislative framework to ensure it is rooted in, and protected by, the law.

The Financial Component

12. There are two aspects of the financial component: the funds necessary to perform adequate regulatory work, and financial restrictions pursuant to employment in the regulatory agency. In both cases, however, there must be a funding mechanism which is transparent and politically accountable.
13. In relation to the first, the source of funding to perform the regulatory task can influence independence in regulatory decision-making. Whether funds for the regulatory agency are derived from tax revenues or are fee-based from licensees, they must be sufficient to transact prescribed regulatory functions, and to support sufficient regulatory safety research. Deregulation of the electricity market in some national programmes has increased industry pressure, both direct and indirect, to reduce costs, and this, in turn, will increase the pressure to reduce the regulatory burden.
14. In relation to the second, it is important to be transparent. For example, when the senior regulators serve a fixed term before moving on to other employment it is useful to define post-employment restrictions to avoid compromising regulatory independence. Restrictions should also be considered for all regulatory staff. Financial disclosure rules should be clearly stated and direct financial involvement through for example share ownership should be prevented.

The Technical Component

15. There should be independence in expressing sound technical safety opinions. In this area regulatory staff should be free to make objective technical decisions. Personnel practices should be transparent, as regulatory personnel are often recruited from the regulated industry. The development of a regulatory culture through training, supervision and transparent regulatory practices is essential.
16. With the aim of avoiding cultural preferences and social conditions unduly affecting the structuring of the inspection programme, the establishment of a code of conduct based on ethical rules and restrictions is recommended. This could include periodic rotation of inspectors; oversight of inspectors by regulatory management; cross-inspection programmes; the use of teams of inspectors; and reliance on objective, written criteria.

The Communication Component

17. The regulatory body must not only have free access to the public whose health and safety it protects it must also be open to the public. This open two-way communication reinforces regulatory credibility. Demonstrable regulatory independence through public access is an essential building block of an effective nuclear safety culture.

The Accountability Component

18. Independence can be reinforced through transparent accountability lines. However Government and the public may wish the Regulatory Body's activities to be scrutinised to ensure it is exercising its responsibilities properly. Advisory committees or government investigative bodies can be useful in providing effective oversight of regulatory decision-making by reinforcing transparency and thus enhancing neutrality and objectivity of the regulator body.

The International Component

19. Nuclear safety is of international concern and hence internationally acceptable standards are seen as desirable. However, the establishment of international nuclear safety standards can provide both a limitation and a support for national regulatory independence. The requirement to comply with international standards can limit the independence of a national regulatory body to set its own standards. It is important, therefore, for the regulatory bodies to participate in the development of international nuclear safety standards.
20. National regulatory bodies should be free to implement rules and procedures which go beyond the internationally accepted standards. However, international standards can help regulators, especially those in developing nuclear programmes to cite international standards as a means of justifying and confirming their national regulatory decision-making.

REGULATORY PROCESS

Introduction

21. A major contribution to the commitment to give nuclear safety the highest priority is to establish a rigorous and transparent process by which the national regulatory body regulates nuclear activities. This process determines the relationship between the regulator and the licensee and defines the scope of regulatory scrutiny. At best, regulatory oversight only comprises an "audit" of licensee self-assessment performance. The size of the audit sample is determined by the results of regulatory inspections and assessments. Therefore, much of the regulator's review of the licensee's performance hinges on the degree of regulatory confidence that can be placed in the licensee's ability to identify and correct its own deficiencies.

THE COMPONENTS OF THE REGULATORY PROCESS

22. A clear statement of the regulatory process should include all regulatory oversight responsibilities. Regulation should be perceived to be reliable and not unjustifiably in a state of transition. Regulatory actions should be fully consistent with written procedures and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear planning and operational process. Any regulations should be based on the best knowledge available from both research and operational experience. Within a regulatory process, it is important to have an ongoing open dialogue between licensees and regulators at several organisational levels to promote a common understanding of the importance of safety issues. Regulation should be transparent, and the public should be kept informed of regulatory decisions.
23. The regulatory process should include a number of key components including oversight and safety responsibilities and transparency.

The Oversight Component

What are the key regulatory processes and role of the regulatory body?

24. Many of the national regulatory bodies interpret and carry out the regulatory process differently. Historical, constitutional, legal, political, institutional, social and cultural developments have ensured diversity in the conduct of regulatory work, and it is important that these differences are recognised as providing acceptable alternative approaches within a strong regulatory programme, within the general principles of good regulation. The prime role of the nuclear regulator is to ensure public and worker safety. To implement this responsibility a decision-making framework that preserves neutrality and objectivity is essential. For a robust national regulatory system, the necessary fundamental elements in nuclear safety regulation are to: establish an effective licensing process (for all phases, including design basis, construction, operation, decommissioning, etc.); issue regulations and guidelines; create an inspection capacity; provide for enforcement of the regulations; have the technical capability to review and assess licensees' safety submissions; promulgate emergency preparedness rules and guidelines; provide for effective incident response mechanisms; have adequately staffed, financed, and independent verification of nuclear safety research; create a regulatory management structure; implement a sufficient and reliable nuclear liability system; and develop the necessary human resources.

The Safety Responsibility Component

Who is responsible for safety?

25. The prime responsibility for the safety of a nuclear installation rests with the holder of the licence, while the responsibility for ensuring that the licensee exercises his responsibility properly rests with the regulators on behalf of the national government. To carry out this responsibility, the regulatory body must have adequate authority, competence, and financial and human resources.
26. The responsibility of the regulator is oversight through the establishment of basic safety principles, enforcement of laws, and development of regulations, to protect the health and safety of the public and employees. The decisions by a regulatory body should be consistent, and should acknowledge the licensee's responsibility for safety. There should be awareness by the licensees that despite continued pressure to reduce resources in search of increased profits, long term survival and efficiency and still depends on robust safety systems.

The Transparency Component

How does a regulator demonstrate transparency effectively and efficiently to political decision makers, stakeholders, and the public?

27. Transparency in regulatory rulemaking, and providing for public information in decision making affecting nuclear safety is very important. Transparency should extend beyond the licensee to decision makers, stakeholders, and the public. The regulator should therefore publish the principles which it uses for decision-making, and information on major decisions, explaining the basis for the regulator's conclusions.

REGULATORY EFFECTIVENESS

Introduction

28. The effectiveness of a regulatory regime is measured in terms of how well it performs and accomplishes its mission. The measure of the effectiveness of a regulator hinges on its actions and processes relative to the performance of the licensee. To be effective there must be a clear understanding of the regulator's purpose, clear industry performance standards, and prescribed areas of focus and jurisdiction. Effectiveness encompasses both policy and technical areas. It should be noted that areas outside jurisdiction of some regulators, such as radiation protection, safeguards, radioactive releases, radioactive waste, environmental protection, and the transport of nuclear materials may still impact on external perceptions of regulatory effectiveness.

Regulatory effectiveness has a number of components covering legal, financial, technical, communication and accountability aspects.

The Legal Component

29. A prerequisite to regulatory effectiveness is to have a regulatory body with effective independence and a stable legal infrastructure. There must be harmony in inter-jurisdictional areas (e.g., federal vs. local, environmental vs. health and safety), and with the mandates of other agencies that have overlapping responsibilities. The regulatory processes needs a graded list of sanctions to suit different situations. Finally, there must be clear linkages between the regulator's authority, as represented in its legal mandates, and regulatory activity.

The Financial Component

30. The source of a regulatory body's funding impacts factors such as its independence and how the regulator is perceived, and therefore has an influence on its actual regulatory effectiveness.
31. The regulatory body must have sufficient resources to ensure appropriate, timely and consistent regulatory actions and processes. The regulatory body must not be subjected to threats to cut its funding if it reaches decisions which may not be palatable to some stakeholders.

The Technical Component

32. Good management, complemented by competent, well-trained and motivated staff, is a critical component of regulatory effectiveness. The regulator needs to act in an efficient, consistent manner, with no excessive time delays, while balancing the interests of all stakeholders. Changing managers or site inspectors periodically can aid regulatory effectiveness, both as measured and as perceived.
33. The drive for efficiency must not impede effectiveness. For instance, effective licensing reviews must be the outcome of clear standards and not just meeting target dates. Clear standards are also required for judging the quality of licensee submittals, which in turn affects both efficiency and effectiveness.
34. To be effective the regulatory body needs to keep a clear focus on safety, using all the methods available to prioritise their actions, such as probabilistic risk insights within a deterministic framework. A minimum, or "baseline," of oversight activities, such as inspection should be established. Consideration should be given to the introduction of

“goal setting” policy on regulations, using time limits and periodic re-evaluations. The regulatory body must be flexible in dealing with unforeseen regulatory issues.

35. Where possible there should be a non-adversarial approach to licensees, and licensee self-assessment should be incorporated into an effective regulatory regime.

The Communication Component

36. An aspect of effective communication is a perception of fairness on the part of the stakeholders. By implementing a system of simple, clear guidance, the regulator can create a common understanding of the regulatory process. Therefore, the regulator must effectively communicate to the licensees through clear standards and definitions, and equally clear thresholds for action.
37. The regulator must communicate equally effectively with the public. To be effective, the regulator must learn to work with the media; must provide training for its regulatory staff in the area of clear communication; and must work to inform the public at large. For instance, the issue of commercial deregulation is an issue which produces outside interest in regulatory effectiveness, and poses challenges for clear communication with all stakeholders.

The Accountability Component

38. The regulatory body must demonstrate to its stakeholders that it is performing its duties effectively and be accountable for its actions. Its enforcement policies should have clear thresholds which are acceptable to its stakeholders. The regulatory body must ensure the right balance in the application of its regulatory powers.
39. Licences, licence conditions and regulations need to be periodically reviewed, to ensure that they achieve their purpose and retain stakeholder support. A means of measuring regulatory effectiveness is to demonstrate that the requirements have had positive outcomes.

POWERS AND SANCTIONS

40. The nuclear industry is one of the most heavily regulated enterprises around the world, due to a number of factors: public perception of the hazardous nature of nuclear energy; specific events (e.g., the Windscale Fire, Three Mile Island, Chernobyl); chronic and acute consequences associated with the misuse of nuclear material; short and long-term costs of accidents to communities; the need for long-term management

of wastes; and historical reasons, such as the military origins of nuclear energy use, and its highly sophisticated technology from the outset.

41. The regulatory body needs a wide array of powers and sanctions to implement the mandate to strictly oversee the nuclear industry, and there is a concomitant higher public expectation for the exercise of those powers and sanctions. The basic aims of the powers and sanctions given to a regulatory body are to ensure the regulator has the power to set the safety outcomes or goals, and has the power to require that the operator to have a safety regime in place to achieve those outcomes.
42. The powers and sanctions which a regulatory body is authorised to exercise contribute to how effective the agency can be in accomplishing its mandate. There are a number of components which encompass the basic requirements for an effective powers and sanctions strategy.

The Legal Component

43. A graded structure of legal powers and sanctions, covering a broad range of nuclear uses, is important to regulatory effectiveness, as is a thorough understanding within the regulatory body of how best to implement them.

The Public Communication Component

44. Public opinion is a potent tool that can be used by the regulator in its exercise of powers and sanctions. The ability to invoke negative publicity can in itself have the potential to 'persuade' the nuclear industry to further improve safety, even though the probabilistic or deterministic safety criteria may already have been satisfied.

The Financial Component

45. Regulatory powers and sanctions should cover plant management and ownership arrangements, to the extent that such arrangements can impact safety (e.g., through dilution of responsibility and cost reduction measures). For instance, regulatory powers and sanctions may need to be exercised due to changes in working conditions, such as foreign ownership; operating the nuclear power plant as a "merchant" operation (i.e., absentee ownership and operation); instituting economies of scale, such as consolidating engineering organisations; and increased use of overtime, which increases worker fatigue. There are also associated liability issues.

The Technical Component

46. The most basic powers and sanctions given to a regulatory body should include: unfettered access for inspection; the power to stop unsafe operation of a nuclear power plant; the power to revoke an operating licence (both an operator's personal licence, and the company's licence, the latter may require approval of a ministry in some countries); and the power to require that decommissioning funds be set aside for power reactors, university reactors and research reactors, and for fuel cycle facilities.
47. The regulator should have available powers which allow it to influence nuclear power plant operators undergoing "facility changes," such as plant organisation and management, particularly in light of the potential for safety degradation due to deregulation, down sizing and the resulting loss of organisational knowledge. Changes should be allowed only after an analysis is made of their impact on the plant, as part of a self-assessment process which focuses on the safety implications of the proposed changes. Depending on national legislation, the regulatory powers will hinge on whether the regulation is "proactive" or "reactive," i.e., whether the regulator or the regulated entity has the burden of proof.
48. The traditional "hands off" regulatory approach may have to change in light of proposed plant management changes. The regulator in a mature nuclear power programme may have to stay focused on how corporate knowledge may be lost in such changes, and how these may impact on safety. For instance, plant management changes may result in contracting and subcontracting activities which may be of safety significance, but the owner must still be held responsible for plant safety.
49. The regulator's powers and sanctions may be affected by its interaction with other government agencies which have overlapping or connected powers and sanctions. Some examples of this are in the areas of unfair treatment of workers/workers rights; environmental protection; and policies regarding worker substance abuse.

The Accountability Component

50. Licensees should be "intelligent customers," capable of evaluating and owning the technical merits of the services being purchased, and being held responsible and accountable for the safety of their plants.
51. The regulator needs to be equally sophisticated in understanding a company's structure, examining staffing practices and organisational work processes (e.g., overtime policies), and relating that understanding to safety issues.

INTERNAL QUALITY ASSURANCE

52. It is often suggested that as the nuclear regulator provides a vital contribution to nuclear safety, they too should use a QA programme to both enhance and demonstrate the quality of their regulatory activities. A quality assurance system (QA), as applied to a nuclear regulatory body, essentially means “Management for Quality,” and should be an integral part of day-to-day operations. This function can be directed to all regulatory processes including those which ensure technical competence and at management systems. The QA or self-assessment capabilities of any organisation have many of the same universal programmatic purposes: inter alia, to review the relevance of various actions to the organisation's overall mission, the effectiveness of the organisation's processes; the coherence and consistency of organisational actions; the costs expended versus the benefits received; identification of areas for improvement; and comparisons to similar organisations. There are a number of components which should be considered in the application of Quality Assurance to a regulatory body.

The Technical Component

53. Just as with licensees, the management of a regulatory body can be enhanced by the existence of a QA auditing body that maintains its independence from day to day management and objectivity. To the extent that such a QA programme can enhance the effectiveness and transparency of the regulatory body, the regulator should make every effort to develop and maintain an effective quality management system. This audit process can be either internal through a designated official or external through an outside auditor.
54. The values and criteria for such a system are similar to those of regulatory effectiveness, to enhance the effectiveness of the regulator while maintaining a focus on the regulatory safety mission. Such audits can focus on the effectiveness of particular functions or systems and draw on specialised expertise to evaluate a particular regulatory decision or a particular technical area, or they can evaluate the overall programme.

The Internal Audit Component

55. All regulatory functions can benefit from an internal audit system. The internal QA manager should be as independent as possible and should report to the highest responsible level of the organisation. The health of the internal QA programme can be influenced by its placement within the organisation, who it reports to, who selects the auditors, who decides the scope of each audit, etc. all revolving around the degree of

independence given to the auditors. The source of the programme budget and budget decisions also can be a major factor.

56. One caution should be pointed out with respect to internal audits. Any area may be over-audited; this caution should be considered particularly when a given process is already undergoing change. An additional audit can cause the change process to bog down or lose direction. However, if properly applied, internal QA audits can be an effective means for improving the organisation from within, rather than relying on external events or external scrutiny to identify areas needing improvement.

The Facilitation Component

57. Third-party participation in QA audits can be vital in ensuring the requisite level of expertise in a given area and provides an independent and objective viewpoint. The methods, structure, and philosophy of a QA group are often similar regardless of the organisation it serves and much can be learned by studying other organisations and audit models.
58. There is also considerable value in formulating cross-sectional peer-review teams with outside consultants or facilitators, to create common understandings, to develop QA strategies, and to share lessons learned. Consultants can also be useful in validating the organisation's own QA assessments. It is also worth considering an international peer review.

The Accountability Component

59. Regulations need to be periodically reviewed, to ensure that they achieve their purpose. A means of measuring regulatory effectiveness is to demonstrate whether requirements have had positive outcomes. Internal quality assurance mechanisms can be used to re-evaluate regulations, processes, and their implementation. Licensee feedback should be integrated in this quality assurance process.

The International Component

60. International benchmarking can be useful in providing relevant data and support in establishing an effective regulatory process. As has been evident in the first Review Meeting of the Contracting Parties to the Convention on Nuclear Safety, peer reviews can increase regulatory effectiveness and serve as a form of benchmarking.